



# United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Viginia 22313-1450 www.uspto.gov

APPLICATION NO.	FI	LING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/885,445	09/885,445 06/21/2001		Robert H. Frater	P 279185 P95US1	2733
909	7590	07/25/2003			
PILLSBUF	RY WINT	HROP, LLP	EXAMINER		
P.O. BOX 10500 MCLEAN, VA 22102				FERKO, KA	THRYN P
				ART UNIT	PAPER NUMBER
				3743	14
				DATE MAILED: 07/25/2003	

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

		$\mathcal{M}$					
,	Application No.	Applicant(s)					
	09/885,445	FRATER ET AL.					
Office Action Summary	Examiner	Art Unit					
	Kathryn Ferko	3743					
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, - Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).  Status	86(a). In no event, however, may a reply be time within the statutory minimum of thirty (30) days rill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	nely filed s will be considered timety. the mailing date of this communication. D (35 U.S.C. § 133).					
1) Responsive to communication(s) filed on 20 J	<u>une 2003</u> .						
2a) This action is FINAL. 2b) ☐ Thi	is action is non-final.						
3) Since this application is in condition for allowa							
closed in accordance with the practice under <i>I</i> <b>Disposition of Claims</b>	ex parte Quayle, 1935 C.D. 11, 4	53 O.G. 213.					
4) Claim(s) 1-126 is/are pending in the application.							
4a) Of the above claim(s) 1-22 and 34-124 is/are withdrawn from consideration.							
5) Claim(s) is/are allowed.							
6)⊠ Claim(s) <u>23-33,125 and 126</u> is/are rejected.							
7) Claim(s) is/are objected to.	7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or	r election requirement.						
Application Papers							
9) The specification is objected to by the Examiner.							
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.							
If approved, corrected drawings are required in reply to this Office action.							
12) The oath or declaration is objected to by the Examiner.							
Priority under 35 U.S.C. §§ 119 and 120							
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).							
a) ☐ All b) ☐ Some * c) ☐ None of:							
1. Certified copies of the priority documents have been received.							
2. Certified copies of the priority documents have been received in Application No							
<ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>							
14)⊠ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).							
a) ☐ The translation of the foreign language provisional application has been received.  15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.							
Attachment(s)							
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Informal I	(PTO-413) Paper No(s) Patent Application (PTO-152)					

Art Unit: 3743

#### **DETAILED ACTION**

## Response to Amendment

This is a response to the amendment dated June 20, 2003. Claims 22-33, 125 and 126 are pending. Amendments to the specification and drawings are acknowledged and accepted.

## Response to Arguments

1. Applicant's arguments with respect to the rejection(s)of claim(s) 23-33 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Venegas in US Patent No. 5,074,297.

## Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 3. Claims 23-28 and 125 are rejected under 35 U.S.C. 102(b)/103(a) as being anticipated by Venegas in US Patent No. 5,047,297.

Venegas discloses a mask (10) for delivering breathable gas to a patient where the mask (10) has a shell (16) having a portion adapted to receive a supply of pressurized breathable gas and a user side, recited in column 1, lines 50-67; a cushion (12, 26) constructed and arranged to contact a user's face in use and provide a seal between the mask and the user's face; headgear (22)

Art Unit: 3743

constructed and arranged to attach the mask shell to the user, as stated in column 1, lines 50-67 and seen in figures 1 and 2; a gusset portion (14) having a first side attached to the user side of the shell, as seen in figure 1; and a mask that is a nasal mask, as seen in figure 1.

A gusset portion that is constructed and arranged such that it can expand and contract within a range of displacement to alter a distance between the mask shell and the cushion where, the gusset portion defines a gusset area exposed to the supply of pressurized breathable gas in use such that the supply of pressurized breathable gas acting on the gusset area provides a component of a contact force F.sub.c of the cushion on the user's face, the force F.sub.c being maintained in approximately constant proportion to the supply of pressurized breathable gas and a total force of the mask on the face Fm being maintained within a range of about 35-108 grams per gf/cm.sup.2 pressure of the supply of pressurized breathable gas over an operating pressure range of the mask; a force Fm that is maintained within a range of about 40-88 grams per gf/cm.sup.2 pressure of the supply of pressurized breathable gas; a force Fm that is maintained within a range of about 50-88 grams per gf/cm.sup.2 pressure of the supply of pressurized breathable gas; and an operating pressure range that is about 4-25 gf/cm.sup.2, are within the scope of the invention and given the structure the system of Venegas would be fully capable of operating within the pressure ranges as claimed.

Application/Control Number: 09/885,445 Page 4

Art Unit: 3743

Further, expansion and contraction of the gusset portion that permits a seal to be maintained between the cushion and the user's face within a range of about plus and minus 8 degrees angular displacement of the mask shell with respect to the user's face is also within the scope of the invention as seen in figures 1-4. Venegas also discloses a gusset portion (14) that includes a single gusset having a flexible sidewall with a generally triangular cross-section when not exposed to the supply of pressurized breathable gas that balloons to a generally rounded cross-section when exposed to the supply of pressurized breathable gas, as recited in columns 2-4 and seen in figures 1-4.

## Claim Rejections - 35 USC § 103

- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. Claims 29-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Venegas in US Patent No. 5,074,297.

Although not explicitly recited, a gusset portion that includes a sidewall having a thickened cross-section at a base of the sidewall, where the thickened cross-section has a generally uniform thickness; and a gusset portion that includes a sidewall having a cross-sectional thickness tapering from a thickened base portion to a thinner portion are also within the scope of the invention, see column 3, lines 10-50. Therefore, it would be obvious to one with ordinary skill in

Application/Control Number: 09/885,445

Art Unit: 3743

the art to provide the gusset portion to have a sidewall having a thickened cross-section at a base of the sidewall, where the thickened cross-section has a generally uniform thickness; and a gusset portion that includes a sidewall having a cross-sectional thickness tapering from a thickened base portion to a thinner portion for the purpose of a proper seal.

Further, element 16 of Venegas acts as a generally rigid backstop of the mask shell for contacting a first sidewall portion of the gusset portion to limit movement of the first sidewall portion extends around substantially an entire periphery of the gusset portion.

Additionally, it is within the scope of the invention to use the mask as a CPAP mask.

#### Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure are as US 2003/0089372 and US 2003/0075180.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Ferko whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Application/Control Number: 09/885,445

Art Unit: 3743

Page 6

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

KF July 21, 2003

> Herry Heinett Superviser Patent Examiner